

Please cancel claims 2, 9 and 12, without prejudice to the presentation of those claims in a continuing application.

REMARKS

Claims 2-15 stand rejected under 35 U.S.C. 103 as being unpatentable over Gennaro, in view of Stetz et al. Upon entering the amendment, claims 3-8, 10, 11 and 13-15 will be pending in the application. Applicants respectfully traverse the rejection of the claims and request reconsideration of the application.

The Amendment

Applicants have deleted claims 2 and 9 and have incorporated the limitations of those claims into claim 15. Applicants have canceled claim 12 and incorporated the limitation of that claim into claim 5. Claims 15 and claim 5, and all claims depending thereon, now require that the propellant gas consist of fluorohydrocarbons and that the plastics coatings applied to the inner walls of the container consist of polytetrafluoroethylene, perfluoroethylenepropylene, or mixtures thereof. As the amendment does not introduce any matter into the claims which has not been subject already to search and examination by the Examiner, it is respectfully requested that the amendment be entered.

The Invention

Applicants claim an aerosol container system which is used to meter and administer pharmaceutically active aerosols supplied in the form of a suspension, the suspension which includes a pharmaceutically active agent (PAA) and a propellant gas which consists of fluorohydrocarbons. The container comprises a container wall, the inner portion of said container wall which defines the interior of the container being coated with a plastics coating consisting of polytetrafluoroethylene, perfluoroethylenepropylene, or mixtures thereof, and a metering valve which is constructed and which functions according to the claim limitations.

As described at page 2 of Applicants' specification, due to the replacement of the fluorochlorohydrocarbon propellant gases with alternative propellant gases, the PAA tends to adhere to and build-up on the inner container wall. This presents a problem with proper administration of the PAA, in that such deposits on the inner wall of the container may result in the desired amount of PAA that is to be administered to the user not being present in the metering

chamber. A further consequence is that the total amount of PAA stored in the container cannot be administered, since a very considerable proportion of the total amount of the PAA introduced into the container remains deposited on the inner wall of the container. Applicants have discovered that this problem may be solved by applying to the "inner" wall of the container a plastics coating consists of polytetrafluoroethylene, perfluoroethylenepropylene, or mixtures thereof.

The Prior Art

Applicants submit that Gennaro is a general reference concerning aerosol packaging, and neither teaches nor suggests Applicants' invention. Applicants respectfully submit that Gennaro suggests that plastic coatings on the inner wall of the aerosol container, in general, are not required. While Gennaro does disclose aluminum aerosol containers which may contain internal coatings. Applicants respectfully submit that Gennaro does not teach or suggest the interaction between the plastic coating, the propellant and the PAA. Accordingly, Applicants respectfully submit that Gennaro does not appreciate nor suggest the problems associated with replacement of the fluorochlorohydrocarbon propellants with fluorohydrocarbon propellants, one of those being deposition of the PAA onto the inner walls of the aerosol container. Accordingly, Applicants respectfully submit that Gennaro neither teaches nor suggests the solution to those problems. Specifically, Gennaro neither discloses nor suggests that the inner wall of the aerosol container must be coated with a plastic consisting of polytetrafluoroethylene, perfluoroethylenepropylene, or mixtures thereof when a suspension comprising a PAA and a fluorohydrocarbon propellant is placed inside the aerosol container..


Applicants respectfully submit that Stetz et al. fails to cure the deficiencies of Gennaro, in that Stetz fails to suggest or teach that, where fluorochlorohydrocarbon propellant gases are replaced with fluorohydrocarbon propellants, one must apply to the inner wall of the aerosol container a plastic coating consisting of polytetrafluoroethylene, perfluoroethylenepropylene, or mixtures thereof. In fact, Stetz is silent as to plastic coatings altogether and therefore can add nothing to the teachings of Gennaro with respect thereto.

Based on all of the foregoing, Applicants respectfully submit that neither Gennaro nor Stetz, alone or in combination, teach or suggest an aerosol container system for metering and administering pharmaceutically active aerosols in the form of suspensions of PAA and a propellant gas consisting of fluorohydrocarbons, which container has applied to the inner wall thereof a plastic

coating consisting of polytetrafluoroethylene, perfluoroethylenepropylene, or mixtures thereof. Accordingly, Applicants respectfully request that the rejection of Claims 2-8, 10, 11 and 13-15 under 35 U.S.C. 103 over Gennaro in view of Stetz et al. be withdrawn and a notice of allowance of the claims be issued.

Respectfully submitted,

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